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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/825,964 | 04/15/2004 | Kenneth T. Heruth | 1023-360US01 | 8232 |

28863 7590 03/23/2009

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| EXAMINER | |
|---|---|
| SMITH, FANGEMONIQUE A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3736 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 03/23/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pairdocketing@ssiplaw.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/825,964 | HERUTH ET AL. | |
| | Examiner | Art Unit | |
| | Fangemonique Smith | 3736 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *20-23,26-33,35-38,40,43-45,53,55,57-62,72 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-23,26-33,35-38,40,43-45,53,55,57-62,72 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/5/08, 10/22/08, 11/20/08, 1/15/09, 2/13/09, 3/12/09.

## DETAILED ACTION

1. This Office Action is responsive to the Remarks filed on January 5, 2009. Examiner acknowledges the amendment of claims 20-23, 26, 28, 29, 35-38, 40, 43, 53, 55, 57, 59-61, 72 and 73; and the cancellation of claims 19, 24, 25, 39, 41, 42, 54 and 56. Claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73 are pending.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatlestad et al. (U.S. Patent Application Publication Number 2005/0042589 A1) in view of Koh et al. (U.S Patent Number 7,207,947).

In regard to claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73, Hatlestad et al. disclose a sleep quality data collection and evaluation device which assess sleep quality based on detected physiological or non-physiological patient conditions. The medical device disclosed by Hatlestad et al. comprises a plurality of sensors which generate a signal as a function of at least one physiological parameter of a patient (paragraphs [0066]-[0070]). The device also includes an implantable device and a microprocessor with memory. The microprocessor monitors a plurality of physiological parameters of the patient based on the signals output by the sensors (paragraphs [0066]-[0082]). The Hatlestad et al. device determines a value of a sleep metric that

indicates a probability of the patient being asleep based on the physiological parameters. Hatlestad et al. disclose using the device to monitor respiratory rates and blood oxygen saturation levels of a patient (paragraphs [0062]-[008l]). The microprocessor disclosed by Hatlestad et al. determines variability and a mean value of at least one of the physiological parameters and determines sleep metric values from the information gathered (paragraphs [0135]-[0162]). The system then determines a value of an overall sleep metric based the values of the plurality of sleep metrics and determines the value of the overall sleep metric by averaging the values of the plurality of sleep metrics (paragraphs [0090]-[0103]). Hatlestad et al. further disclose the device including a memory used to store threshold values, wherein the processor compares the value of the sleep metrics to the threshold values and determines whether the patient is asleep based on the comparison (paragraphs [0080]-[0103]). Hatlestad et al. disclose a means for monitoring a plurality of physiological parameters of a patient and a means for determining a value of a sleep metric indicates based on the physiological parameters. The Hatlestad et al. device further includes a means for generating at least one signal as a function of the physiological parameters, wherein the means for monitoring comprises means for monitoring the physiological parameters based on the signal. The means for determining a sleep metric expressed by Hatlestad et al. comprises means for determining a value for each of a plurality of sleep metrics, each of the plurality of values determined based on a respective one of the physiological parameters (paragraphs [0135]-[0162]). The device determines a value of a sleep metric by determining a value of an overall sleep metric based the values of the plurality of sleep metrics and a comparison of the value of the sleep metric to a threshold value. Additionally, Hatlestad et al. disclose a means for delivering a therapy to the patient and means for controlling delivery of a

therapy to the patient by the therapy delivery means based on the determination of whether the patient is asleep. The Hatlestad et al. device has a storage mechanism for storing values to access at a later time. Hatlestad et al. suggest the implantable medical device may be an implantable neurostimulator (paragraph [0059]). In regard to the claims, Hatlestad et al. disclose the features of the Applicant's invention as described above. Although Hatlestad et al. disclose the use of the sensors and processor to determine a sleep state including arousal of the patient, the Hatlestad et al. reference does not specifically disclose how the sleep metric values indicate a non-binary probability of the sleep state of the patient. Koh et al. disclose a system and method for detecting circadian states using an implantable medical device. The system disclosed by Koh et al. includes determining several blood carbon dioxide and other parameters to detect circadian states of a patient including $pCO_2$ levels per breathing cycle, end tidal $CO_2$, minute ventilation and activity levels. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a sleep quality data collection and evaluation device which assess sleep quality based on detected physiological or non-physiological patient conditions, similar to that disclosed by Hatlestad et al., to include a device which delivers a sleep metric value which indicates a non-binary probability of the sleep state of the patient, similar to that disclosed by Koh et al., to provide a method which includes several parameters to assist with determining the sleep state of a patient.

### *Response to Arguments*

4. Applicant argues the prior art references fail to disclose an implantable device, which returns a non-binary sleep metric indicating a probability of a patient being asleep. Applicant's

arguments filed January 5, 2009 with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736